

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BOSTON SCIENTIFIC CORPORATION	)	
and BOSTON SCIENTIFIC SCIMED, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 05-768 (SLR)
	)	
CONOR MEDSYSTEMS, INC.,	)	
	)	
Defendant.	)	

**EXHIBITS TO OPENING BRIEF IN  
SUPPORT OF CONOR'S MOTION TO STAY**

MORRIS, NICHOLS, ARSHT & TUNNELL  
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January 3, 2006



## EXHIBIT A



# **FORM 10-Q**

## **CONOR MEDSYSTEMS INC – CONR**

**Filed: November 14, 2005 (period: September 30, 2005)**

Quarterly report which provides a continuing view of a company's financial position

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## EXHIBIT A

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## PART I.

### FINANCIAL INFORMATION

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## PART I.

### FINANCIAL INFORMATION

#### Item 1. Financial Statements

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

#### Item 4. Controls and Procedures

## PART II.

### OTHER INFORMATION

#### Item 1. Legal Proceedings

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

#### Item 6. Exhibits

### SIGNATURE

#### EX-31.1

#### EX-31.2

#### EX-32.1



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2005

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-51066

**CONOR MEDSYSTEMS, INC.**  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

94-3350973  
(I.R.S. Employer  
Identification Number)

1003 Hamilton Court  
Menlo Park, California 94025  
(Address of Principal Executive Offices, including Zip Code)

(650) 614-4100  
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The registrant had 33,672,487 shares of Common Stock, \$0.001 par value per share, outstanding as of October 31, 2005.

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CONOR MEDSYSTEMS, INC.  
FORM 10-Q  
FOR THE QUARTER ENDED SEPTEMBER 30, 2005  
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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## Conor Medsystems, Inc.

## Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	September 30, 2005	December 31, 2004
	(unaudited)	(Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 97,142	\$ 117,676
Accounts receivable	986	—
Inventories	1,541	53
Prepaid expenses and other current assets	1,125	1,039
Total current assets	100,794	118,768
Property and equipment, net	4,182	1,716
Restricted cash	172	170
Other assets	795	235
Total assets	\$ 105,943	\$ 120,889
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,301	\$ 1,961
Accrued compensation	1,825	892
Accrued clinical development liabilities	1,009	729
Accrued legal expenses	1,795	12
Other accrued liabilities	1,066	422
Deferred rent	65	124
Liability for early exercise of stock options – current portion	105	107
Total current liabilities	9,166	4,247
Liability for early exercise of stock options	172	251
Commitments and contingencies (Notes 1 and 3)		
Stockholders' equity:		
Common stock; \$0.001 par value; 150,000 shares authorized at September 30, 2005 and December 31, 2004; 33,285 and 31,961 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	33	32
Additional paid-in-capital	196,901	186,269
Accumulated other comprehensive income/(loss)	122	(32)
Deferred stock compensation	(17,805)	(25,367)
Accumulated deficit	(82,646)	(44,511)
Total stockholders' equity	96,605	116,391
Total liabilities and stockholders' equity	\$ 105,943	\$ 120,889

See accompanying notes

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## Conor Medsystems, Inc.

**Condensed Consolidated Statements of Operations**  
(In thousands, except per share amounts)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Product sales	\$ 1,045	\$ —	\$ 1,369	\$ —
Cost of sales	2,303	—	3,144	—
Gross profit	(1,258)	—	(1,775)	—
Operating expenses:				
Research and development (1)	7,722	4,620	21,828	11,877
General and administrative (1)	6,375	2,383	16,544	4,101
Total operating expenses	14,097	7,003	38,372	15,978
Loss from operations	(15,355)	(7,003)	(40,147)	(15,978)
Interest income	841	119	2,309	215
Other expense	(49)	—	(297)	—
Net loss	(14,563)	(6,884)	(38,135)	(15,763)
Accretion to redemption value of redeemable convertible preferred stock	—	(833)	—	(2,434)
Deemed dividend upon issuance of Series E convertible preferred stock	—	(23,435)	—	(23,435)
Net loss attributable to common stockholders	\$(14,563)	\$(31,152)	\$(38,135)	\$(41,632)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.44)	\$ (8.22)	\$ (1.16)	\$ (11.29)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	33,170	3,789	32,903	3,687
(1) Includes non-cash stock-based compensation expense as follows:				
Research and development	\$ 1,536	578	\$ 3,820	\$ 931
General and administrative	1,756	1,501	5,317	1,868
Total	\$ 3,292	\$ 2,079	\$ 9,137	\$ 2,799

See accompanying notes

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## Conor Medsystems, Inc.

## Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2005	2004
<b>Operating activities</b>		
Net loss	\$ (38,135)	\$ (15,763)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	683	155
Amortization of deferred stock compensation	7,147	2,489
Loss on disposal of property and equipment	66	16
Stock compensation expense for consulting services	1,990	310
Accrued interest income on notes receivable	—	(5)
Forgiveness of officer loan receivable	—	111
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(87)	(602)
Accounts receivable	(1,028)	—
Inventories	(1,447)	—
Other assets	(560)	(151)
Accounts payable	1,374	588
Accrued compensation	944	89
Accrued clinical development liabilities	280	(74)
Other accrued liabilities	2,440	(157)
Deferred rent	(59)	22
Net cash used in operating activities	(26,392)	(12,972)
<b>Cash flows from investing activities:</b>		
Transfers to restricted cash	(2)	(32)
Capital expenditures	(3,109)	(1,076)
Net cash used in investing activities	(3,111)	(1,108)
<b>Financing activities:</b>		
Proceeds from issuance of common stock, including early exercise of stock options	8,977	334
Proceeds from issuance of redeemable convertible preferred stock, net	—	38,910
Net cash provided by financing activities	8,977	39,244
Effect of exchange rate changes on cash and cash equivalents	(8)	—
Net (decrease) increase in cash and cash equivalents	(20,534)	25,164
Cash and cash equivalents at beginning of period	117,676	22,389
Cash and cash equivalents at end of period	\$ 97,142	\$ 47,553
<b>Supplemental schedule of noncash transactions</b>		
Accretion to redemption value of redeemable convertible preferred stock	\$ —	\$ 2,434
Deferred stock compensation, net of terminations	\$ (723)	\$ 26,561
Deemed dividend to redeemable convertible preferred stockholders	\$ —	\$ 23,435

See accompanying notes

**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**1. Organization and Summary of Significant Accounting Policies**

***Organization and Business***

Conor Medsystems, Inc. (the "Company") was incorporated on October 25, 1999 and is developing innovative controlled vascular drug delivery technologies. Historically, the Company's activities have consisted primarily of recruiting personnel, raising capital and performing product development. The Company was in the development stage through 2004. In 2005, the Company began commercializing its CoStar<sup>™</sup> stent in certain countries in Asia and Latin America. Accordingly, the Company is no longer in the development stage as of September 30, 2005.

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods indicated.

The condensed consolidated balance sheet as of December 31, 2004 is derived from the Company's audited consolidated financial statements as of December 31, 2004, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2004, filed with the Securities and Exchange Commission on March 31, 2005, but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

The unaudited condensed consolidated financial statements and the accompanying notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2004. Operating results for the three and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for any other interim period or for the full fiscal year ending December 31, 2005. Stockholders are encouraged to review the Company's Annual Report on Form 10-K for a broader discussion of the Company's business and the risks inherent therein.

***Initial Public Offering***

On December 14, 2004, the Company completed its initial public offering of 6,000,000 shares of its common stock at a public offering price of \$13.00 per share. Net cash proceeds from the initial public offering were approximately \$70.3 million after deducting underwriting discounts, commissions and other offering expenses. In connection with the closing of the initial public offering, all of the Company's shares of Series A, B, C, D and E redeemable convertible preferred stock outstanding at the time of the offering were automatically converted into 21,534,150 shares of common stock.

On January 7, 2005, the underwriters of the Company's initial public offering exercised in full their over-allotment option to purchase 642,000 shares of the Company's common stock. On January 7, 2005, the Company received net cash proceeds of approximately \$7.7 million after deducting underwriting discounts, commissions and other offering expenses.



The Company is aware of patents owned by third parties, to which it does not have licenses, which relate to, among other things, the use of paclitaxel to treat restenosis, stent structure, catheters used to deliver stents, stent manufacturing processes and composition of materials used on or with stents. For example, Boston Scientific Corporation owns a series of patents that claim the use of paclitaxel to treat restenosis generally and also to treat restenosis via a stent. In addition, Angiotech Pharmaceuticals, Inc. is the owner of a number of patents, and has licensed from the U.S. government a number of other patents, that also claim the use of paclitaxel coated stents to treat angiogenesis and restenosis. Boston Scientific, Johnson & Johnson, Guidant Corporation and other parties also own other patents that may have a material adverse affect on the Company. On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific (as Angiotech's licensee) initiated legal proceedings against the Company in the District Court in the Hague, Netherlands seeking a declaration that the Company's CoStar stent infringes Angiotech's patent rights. In the suit, Angiotech and Boston Scientific are also seeking orders, among other things, preventing the Company from commercializing its CoStar stent in many European countries and requiring the Company to pay damages. Also, on November 8, 2005, Boston Scientific and Boston Scientific Scimed, Inc. (Scimed) initiated legal proceedings against the Company in the District Court for the District of Delaware seeking a judgment that the Company's CoStar stent infringes U.S. Patent No. 5,922,021, one of the Jang patents assigned to Boston Scientific. In the suit, Boston Scientific and Scimed are also seeking orders, among other things, preventing the Company from commercializing its CoStar stent in the United States and requiring the Company to pay damages. Based on the prolific litigation that has occurred in the stent industry and the fact that the Company may pose a competitive threat to other large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, the Company believes that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of the Company's CoStar stent. Any lawsuit could seek to enjoin, or prevent, the Company from commercializing its CoStar stent and may seek damages from the Company, and would likely be expensive for the Company to defend against. The Company has also received letters from third parties, some of whom have been actively involved in coronary stent litigation, asserting that they may have rights to patents that are relevant to the Company's operations or its stent platform and requesting the initiation of discussions. In the event a court determines that the Company infringes any valid claim in a patent held by a third party, the Company expects that such a determination would have a material adverse effect on its results of operations, financial condition and liquidity, and that the Company may, among other things, be required to pay substantial damages, cease the development, manufacture, use and sale of products that infringe the patent rights of others, including its CoStar stent, expend significant resources to redesign the Company's technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible, discontinue manufacturing or other processes incorporating infringing technology, and/or obtain licenses to the infringed intellectual property. The Company believes that it is unlikely that it would be able to obtain a license to any necessary patent rights controlled by companies, like Boston Scientific, against which it would compete directly. In addition, the Company's competitors have significant resources to devote to litigation against the Company, and the Company may need to expend significant resources to defend against such litigation. The Company could require significant additional funds to bear the costs of this litigation, regardless of whether the Company prevails. The Company's ability to continue to operate under its current operating plan could be impaired if such funds are not available. Since the Company's costs in connection with any such litigation will vary greatly depending on the nature and timing of the litigation, it is not possible for the Company to estimate the effect of such costs on its financial condition and results of operations. Amounts, ultimately payable, if any, resulting from an adverse outcome of any of these matters cannot be reasonably estimated at this time.

#### ***Foreign Currency Translation***

The functional currency of the Company's subsidiaries in Ireland is the euro. Foreign assets and liabilities are translated into U.S. dollars at the quarter-end exchange rates, while components of the statement of operations are translated using average exchange rates in effect throughout the year. Gains and losses from foreign currency transactions are included in the condensed consolidated statements of operations. Foreign currency translation adjustments are included as a component of stockholders' equity.

**Revenue Recognition**

The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, and collectibility is reasonably assured. Product sales to date have been to the Company's distributors and revenue from such product sales has been recognized in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition ("SAB 104"). The Company's distributors have no price protection or rights of return.

**Warranties**

The Company warrants products shipped against defects in design, material and workmanship. The Company estimates the costs that may be incurred under its warranties and records a liability in the amount of such estimated costs at the time the product is sold. Factors that affect the Company's warranty liability include the number of units sold, anticipated rate of warranty returns and cost per return. The Company periodically assesses the adequacy of its recorded warranty liability and based upon the outcome of this assessment, records any changes in the estimated warranty liability. To date, the warranty expense that has been included in cost of goods sold, has not been material.

**Inventories**

Inventories are stated at the lower of cost (first in, first out) or market. The Company provides for excess and obsolete inventories based on estimated forecasts of demand. Inventories are summarized as follows (in thousands):

	September 30, 2005	December 31, 2004
Raw materials	\$ 472	\$ 53
Work in progress	1,066	—
Finished goods	3	—
<b>Total Inventory</b>	<b>\$ 1,541</b>	<b>\$ 53</b>

**Stock-Based Compensation**

The Company issues stock options to its employees and outside directors and provides employees the right to purchase the Company's common stock pursuant to stockholder approved stock option and employee stock purchase plans. The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB Opinion No. 25"), Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123").

The Company estimates the fair value of its options and employee stock purchase plan shares using the Black-Scholes option pricing model, which is one of several methods that can be used to estimate option and share values. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. The Company's options have characteristics significantly different from traded options, and changes in the subjective input assumptions can materially affect the fair value estimates.



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The fair value of options granted was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	3.92%	3.40%	3.83%	3.25%
Volatility	0.7	0.7	0.7	0.7
Expected life	5 Years	5 Years	5 Years	5 Years

The fair value of employee stock purchase plan shares was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Dividend yield	0%	N/A	0%	N/A
Risk-free interest rate	3.09%	N/A	3.09%	N/A
Volatility	0.7	N/A	0.7	N/A
Expected life	1.35 Years	N/A	1.35 Years	N/A

During 2003 and 2004, stock options were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation of \$30.5 million was recorded during 2003 and 2004 in accordance with APB Opinion No. 25. The deferred stock compensation will be amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. The related stock-based compensation expense was \$2.4 million and \$2.0 million during the three months ended September 30, 2005 and 2004, respectively. During the nine months ended September 30, 2005 and 2004, the related stock-based compensation expense was \$7.1 million and \$2.5 million, respectively.

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The information regarding pro forma net loss as required by SFAS No. 123, as amended, has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan shares under the fair-value method. The table below illustrates the effect on net loss attributable to common stockholders and net loss per share attributable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss attributable to common stockholders – as reported	\$(14,563)	\$(31,152)	\$(38,135)	\$(41,632)
Add: Stock-based employee compensation expense included in reported net loss	2,397	1,974	7,147	2,489
Deduct: Stock-based employee compensation expense determined under the fair value method	(3,176)	(2,097)	(8,601)	(2,680)
Net loss attributable to common stockholders – pro forma	\$(15,342)	\$(31,275)	\$(39,589)	\$(41,823)
Basic and diluted net loss per share attributable to common stockholders – as reported	\$ (0.44)	\$ (8.22)	\$ (1.16)	\$ (11.29)
Basic and diluted net loss per share attributable to common stockholders – pro forma	\$ (0.46)	\$ (8.25)	\$ (1.20)	\$ (11.34)

Stock compensation arrangements with non-employees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement as the underlying options vest.

The following table illustrates the weighted-average assumptions for the Black-Scholes option pricing model used in determining the fair value of options granted to non-employees:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	4.16%	4.34%	4.04%	4.34%
Volatility	0.7	0.7	0.7	0.7
Contractual term	8 years	10 years	9 years	10 years

**Recent Accounting Pronouncement**

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123R") which is a revision of SFAS No. 123, and supersedes APB Opinion 25. SFAS No. 123R requires all share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values, beginning with the first annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, recognizes no compensation cost for employee stock options.

Under SFAS No. 123R, the Company must determine the appropriate fair value model and related assumptions to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is currently evaluating the requirements of SFAS No. 123R as well as option valuation methodologies related to its employee and director stock options and employee stock purchase plan. Although the Company has not yet determined the method of adoption or the effect of adopting SFAS

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No. 123R, it is expected that the adoption of SFAS No. 123R will have a material impact on the Company's consolidated results of operations. The impact of adoption of SFAS No. 123R cannot be predicted at this time because it will depend on, among other things, the levels of share-based payments granted in the future, the method of adoption and the option valuation method used. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation costs to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* ("SFAS No. 154"), a replacement of APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS No. 154 changes the requirements related to accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and changes required by a new accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. Under SFAS No. 154, the Company must record the impact of a change in accounting principle retrospectively to financial statements of prior periods. Previously, the guidance allowed the recording of the impact of an accounting change in the current period's net income as a cumulative effect adjustment. SFAS No. 154 is effective for the Company beginning January 1, 2006. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's consolidated earnings, financial position or cash flows.

## 2. Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, redeemable convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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The following table presents the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
<b>Historical</b>				
Numerator:				
Net loss attributable to common stockholders	<u>\$(14,563)</u>	<u>\$(31,152)</u>	<u>\$(38,135)</u>	<u>\$(41,632)</u>
Denominator:				
Weighted-average common shares outstanding	33,569	4,064	33,341	3,899
Less weighted average shares subject to repurchase	<u>(399)</u>	<u>(275)</u>	<u>(439)</u>	<u>(212)</u>
Denominator for basic and diluted net loss per share attributable to common stockholders	<u>33,170</u>	<u>3,789</u>	<u>32,902</u>	<u>3,687</u>
Basic and diluted net loss per share attributable to common stockholders	<u>\$ (0.44)</u>	<u>\$ (8.22)</u>	<u>\$ (1.16)</u>	<u>\$ (11.29)</u>
<b>Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation:</b>				
Redeemable convertible preferred stock	—	21,445	—	21,445
Common shares subject to repurchase	371	411	371	411
Options to purchase common stock	5,901	4,782	5,901	4,782
Warrants to purchase common and preferred stock	—	590	—	590
	<u>6,272</u>	<u>27,228</u>	<u>6,272</u>	<u>27,228</u>

**3. Commitments and Contingencies****Operating Leases**

The Company leases certain real and personal property under noncancelable operating leases. Future minimum payments under these leases as of September 30, 2005 were as follows (in thousands):

Years ending December 31,	
2005 (remainder of year)	\$ 295
2006	1,077
2007	981
2008	808
2009	346
Thereafter	1,796
	<u>\$5,303</u>

In addition to these minimum lease payments, the Company is required to pay its share of operating expenses related to property taxes, insurance and routine maintenance in connection with its facility leases. Rent expense under the operating leases was approximately \$0.2 million and \$0.1 million for the three months ended September 30, 2005 and 2004, respectively, and approximately \$0.7 million and \$0.4 million for the nine months ended September 30, 2005 and 2004, respectively.

In February 2005, the Company entered into a ten-year lease, which has an option for an additional ten year term, for an approximately 27,000 square foot permanent manufacturing facility in Athlone, Ireland. This facility includes an approximately 5,000 square foot clean room. Lease payments are fixed for a period of five years, with provisions for annual adjustments for market changes, for the duration of the lease.

In March 2005, the Company entered into an amendment of the lease agreement for the Company's current headquarters in Menlo Park, California. The amendment provides for an additional approximately 26,000 square feet of space in a building adjacent to the Company's current headquarters and extends the term of the Company's lease for an additional year to August 2008.

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On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against the Company in the District Court in the Hague, Netherlands, seeking: a declaration that the Company's CoStar stent infringes European Patent No. (EP) 0 706 376 B1 in the Netherlands and other countries designated in EP 0 706 376 B1; an order that the Company and its affiliates cease any infringement of EP 0 706 376 B1 in the Netherlands and other designated European countries; an order that the Company not use its CE marketing approval, if obtained by the Company, for three years or for a period of time which the District Court deems appropriate and/or at the choice of Boston Scientific and Angiotech; an order requiring the Company to withdraw all information and documentation concerning the clinical trials the Company has conducted in the Netherlands from all relevant regulatory authorities worldwide; an order requiring the Company to pay 2,460 euros per sale of its CoStar stent in Europe or, at the choice of Boston Scientific and Angiotech, 2,460 euros per day that the Company does not comply; an order that the Company indemnify Boston Scientific and Angiotech or surrender its profit on sales of its CoStar stent in countries covered by EP 0 706 376 B1; and an order that the Company pay the costs of the proceedings. A scheduling hearing has been set for April 2006. A trial date for these proceedings has not yet been set. The Company is unable to predict the outcome of these proceedings.

On February 18, 2005, the Company initiated proceedings against Angiotech and the University of British Columbia in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376 B1 based on the grounds that all claims of the patent either lack novelty or are obvious in light of the state of scientific knowledge at the priority date of the patent. The trial began on October 4, 2005, and the High Court of Justice is expected to hear the parties' closing arguments in mid December 2005. The Company anticipates that the High Court of Justice will deliver its decision in early 2006. The Company is unable to predict the outcome of these proceedings.

On March 31, 2005, the Company filed an Application to Revoke Australian Patent Nos. 728873, 771815 and 693797 owned by Angiotech and University of British Columbia in the Federal Court of Australia (Victoria District Registry), on the bases, among others, that the patents are invalid in light of the state of scientific knowledge as of the priority date of the patents and that they are not enabled for the claimed subject matter. A trial date for these proceedings has been set for June 5, 2006. The Company is unable to predict the outcome of these proceedings.

**4. Subsequent Events**

On October 14, 2005, the Company adopted a Change of Control Severance Benefit Plan for the benefit of all non-executive employees. Pursuant to the Change of Control Severance Benefit Plan, if one month prior to or within thirteen months after the effective date of a change of control of the Company, the employee is terminated without cause or the employee is constructively terminated, the employee is entitled to, subject to certain conditions, (1) receive a severance payment, (2) continuation of benefits for three months and (3) full acceleration of option vesting.



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On November 8, 2005, Boston Scientific and Boston Scientific Scimed, Inc. (Scimed) initiated legal proceedings against the Company in the District Court for the District of Delaware seeking a judgment that the Company's CoStar stent infringes U.S. Patent No. 5,922,021, one of the Jang patents assigned to Boston Scientific. In the suit, Boston Scientific and Scimed are also seeking orders, among other things, preventing the Company from commercializing its CoStar stent in the United States and requiring the Company to pay damages. The Company is unable to predict the outcome of these proceedings.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

### Overview

We develop innovative controlled vascular drug delivery technologies. We have initially focused on the development of drug eluting stents to treat coronary artery disease. Our clinical efforts are currently focused on the commercialization of our CoStar™ stent, which is a cobalt chromium paclitaxel eluting stent, for the treatment of restenosis.

Historically, we have devoted substantially all of our resources to developing our stent platform, raising capital and preparing for the commercialization of our CoStar stent. We have pursued a clinical development strategy of using our stents to demonstrate that the drug inlay design of our stents permits us to control drug release kinetics, to establish the safety of our stent design, to demonstrate that drug release kinetics can have a direct impact on clinical outcomes and to establish the basis for regulatory approval of our CoStar stent in the United States and Europe.

In early 2003, we initiated our PISCES study to evaluate the safety and performance of paclitaxel delivered with different release kinetics and doses using our stainless steel stent. We completed enrollment of 191 patients in late 2003 and announced twelve-month follow-up data in March 2005. The most favorable formulations from our PISCES study are the focus of our subsequent EuroSTAR and COSTAR I trials, as well as our U.S. pivotal clinical trial, which are designed to evaluate our CoStar stent. The COSTAR I trial began in late 2003. During 2004 and 2005, we presented four- and twelve-month follow-up data for all three formulation groups in our COSTAR I trial. The EuroSTAR trial began in early 2004. In March 2005, we announced six-month follow-up data from the first arm of our EuroSTAR trial, and

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May 2005, we announced twelve-month follow-up data from the first arm of our EuroSTAR trial. In October 2005, we announced six-month follow-up data from the second arm of our EuroSTAR trial. The EuroSTAR trial served as our pivotal trial to support our submission in the first quarter of 2005 of an application to a designated Notified Body in the European Community, which is one of the steps we must undertake prior to marketing our CoStar stent in the European Community. In March 2005, we received conditional approval of our investigational device exemption, or IDE, application from the FDA to permit the commencement of our U.S. pivotal clinical trial, COSTAR II, which is designed to evaluate our CoStar stent against a conventional drug eluting stent. In May 2005, we announced that the first patient had been enrolled in our COSTAR II trial. We have not yet received any government regulatory approvals necessary to commercialize our CoStar stent. If our clinical trials proceed as scheduled and the outcomes of these clinical trials are favorable, we anticipate receiving regulatory approval for our CoStar stent in the European Community in late 2005 or early 2006 and in the United States in late 2007. We could be delayed by adverse results or regulatory complications, and we may never achieve regulatory approval.

If we obtain the necessary regulatory approval, we plan to pursue commercialization of our CoStar stent in the United States with our own sales force and internationally through distribution arrangements. We entered into an agreement with Biotronik AG in May 2004 to distribute our CoStar stent in countries outside of the United States, Japan, Australia, New Zealand and Korea and certain other countries. In July 2004, we entered into an agreement with Interventional Technologies, Pvt., Ltd., or IVT, to distribute our UniStar™ cobalt chromium bare-metal stent and our CoStar stent in India, Pakistan, Bangladesh, Sri Lanka, Kenya and Tanzania. In November 2004, we entered into agreements with affiliates of St. Jude Medical, Inc. to distribute our UniStar stent and CoStar stent in Japan, Korea, New Zealand and Australia. A decision to seek regulatory approval of, or to sell, our CoStar stent has not yet been made in respect to all of these countries. In the first half of 2005, we began selling commercial units of our CoStar stent in certain countries in Asia and Latin America pursuant to our distribution agreements. We do not expect sales of our CoStar stent in these countries to be significant during 2005, and we do not expect to generate any revenues from sales of our UniStar stent. No regulatory approval is currently required to market our CoStar stent in the countries in which we are currently commercializing our CoStar stent. However, the Indian Ministry of Health has indicated that it will adopt a regulatory framework for medical devices in India. While Indian Ministry of Health officials continue to debate the framework to be adopted, our distributor's ability to commercialize our CoStar stent in India has been limited. We believe that receiving CE Mark for the CoStar stent may reduce these limitations. However, if we are required to obtain some form of license or regulatory approval in addition to CE Mark from Indian regulatory agencies, our distributor's ability to commercialize in India may be limited until such license or regulatory approval is obtained. We have established manufacturing capacity in Athlone, Ireland to manufacture commercial quantities of our CoStar stent, initially for sale outside of the United States, and we are currently in the process of preparing the facility for our planned commercial launch in the European Community.

We were incorporated in Delaware in October 1999 and have a limited operating history. To date, we have not generated significant revenues, and we have incurred net losses in each year since our inception. We anticipate that we will continue to incur net losses for the next several years as we develop new products, expand our clinical development team and corporate infrastructure and prepare for the potential broader commercialization of our CoStar stent. We have financed our operations primarily through private placements of preferred stock and convertible promissory notes, as well as through our initial public offering of our common stock. In July and August 2004, we raised aggregate net cash proceeds of \$38.9 million in a private placement of 6,711,431 shares of our Series E convertible preferred stock. In December 2004 and January 2005, we raised net cash proceeds of \$78.1 million, after deducting underwriting discounts, commissions, and other offering expenses, in our initial public offering of our common stock.

Table of Contents**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States for interim financial reporting. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including those related to stock-based compensation and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, filed with the SEC on March 31, 2005.

**Financial Operations*****Revenues***

In the first half of 2005, we began commercializing our CoStar stent in certain countries in Asia and Latin America. Prior to February 2005, we had not generated any revenues from the sale of our stents. We do not expect sales of our CoStar stent in these countries to be significant during 2005, and we do not expect to generate significant product sales until we successfully obtain marketing approval for and begin selling our CoStar stent in the European Community. We expect that revenues from the sales of our CoStar stent will fluctuate from quarter to quarter.

***Cost of Sales***

Cost of sales is composed of the material, labor, overhead and transportation costs of production and variances associated with inefficiencies in manufacturing. We expect that as our production processes mature and volumes increase, our cost of sales as a percent of product sales will decline.

***Research and Development Expenses***

Our research and development expenses primarily consist of clinical and regulatory expenses, including pre-clinical and clinical trial costs and the cost of manufacturing clinical supplies. Research and development costs also consist of employee compensation, supplies and materials, consultant services, facilities, and non-cash stock-based compensation. We expense research and development costs as they are incurred. We expect our research and development expenses to increase significantly as we complete the development of our CoStar stent, research new product opportunities, conduct additional clinical trials and hire additional employees. We anticipate that the cost of completing our EuroSTAR trial will be approximately \$1.0 million. If our COSTAR II trial proceeds as currently planned, we anticipate that it will cost at least \$15.0 million to complete. In addition, we plan to conduct additional clinical trials using our CoStar stent as well as other drug eluting stents that we are currently developing.

***General and Administrative Expenses***

Our general and administrative expenses consist primarily of compensation for executive, finance and administrative personnel and non-cash stock-based compensation. Other significant costs include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain protection for the intellectual property related to our stent technology. We expect our general and administrative expenses to increase substantially due to the costs associated with operating as a



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publicly-traded company, costs associated with defending patent infringement claims asserted against us and the costs associated with the infrastructure necessary to support the commercialization of our product candidates.

**Results of Operations**

**Three and Nine Months Ended September 30, 2005 and 2004**

***Revenues***

Revenues from product sales were \$1.0 million and \$0 for the three months ended September 30, 2005 and 2004, respectively. Revenues from product sales were \$1.4 million and \$0 for the nine months ended September 30, 2005 and 2004, respectively. Product sales in 2005 were the result of shipments of our CoStar stent to our distributors. We have not generated any revenues from the sale of our UniStar stent, and prior to February 2005, we had not generated any revenues from the sale of our CoStar stent.

***Cost of Sales***

Cost of sales was \$2.3 million and \$0 for the three months ended September 30, 2005 and 2004, respectively. Cost of sales was \$3.1 million and \$0 for the nine months ended September 30, 2005 and 2004, respectively. During the nine months ended September 30, 2005, we began production of our CoStar stent for commercial sale. The cost of sales for the three and nine months ended September 30, 2005 is representative of the production costs and variances associated with the early commercialization of our CoStar stent. The cost of sales for the three months or nine months ended September 30, 2005 is not necessarily indicative of production costs in future periods. Prior to February 2005, we had no product shipments and no associated cost of sales.

***Research and Development Expenses***

Research and development expenses were \$7.7 million and \$4.6 million for the three months ended September 30, 2005 and 2004, respectively. The \$3.1 million increase was primarily due to \$1.7 million of higher payroll and related expenses as we increased research and development personnel, an increase of \$0.8 million in non-cash non-employee stock-based compensation expenses, and higher clinical trial expenses of \$0.3 million for such items as supplies, tooling, consulting and outside services.

Research and development expenses were \$21.8 million and \$11.9 million for the nine months ended September 30, 2005 and 2004, respectively. The \$9.9 million increase was primarily due to \$5.0 million of higher payroll and related expenses as we increased research and development personnel, higher clinical trial expenses of \$1.9 million for such items as supplies, tooling, consulting and outside services, an increase of \$1.5 million in non-cash non-employee stock-based compensation expenses, and an increase of \$1.4 million in non-cash employee stock-based compensation expenses.

***General and Administrative Expenses***

General and administrative expenses were \$6.4 million and \$2.4 million for the three months ended September 30, 2005 and 2004, respectively. The \$4.0 million increase was primarily due to \$2.1 million of higher expenses related to professional services for legal, audit and other consulting services, an increase of \$0.7 million in trade show, promotional, franchise tax and other expenses and \$0.6 million of higher payroll and related expenses as we increased management and administrative personnel.

General and administrative expenses were \$16.5 million and \$4.1 million for the nine months ended September 30, 2005 and 2004, respectively. The \$12.4 million increase was primarily due to \$5.2 million of higher expenses related to professional services for legal, audit and other consulting services, an increase of \$3.3 million in non-cash employee stock-based compensation expenses, \$1.7 million of higher payroll and related expenses as we increased management and administrative personnel and an increase of \$1.5 million in trade show, promotional, franchise tax and other expenses.

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**Interest Income**

Interest income was \$0.8 million and \$0.1 million for the three months ended September 30, 2005 and 2004, respectively, and \$2.3 million and \$0.2 million for the nine months ended September 30, 2005 and 2004, respectively. The increases in both periods were primarily due to higher cash balances resulting from our initial public offering of common stock and higher yields on our investments.

**Other Expense**

Other expense was \$49,000 and \$0 for the three months ended September 30, 2005 and 2004, respectively, and \$0.3 million and \$0 for the nine months ended September 30, 2005 and 2004, respectively. The increases in both periods were due to the currency translation adjustments when translating intercompany balances from the euro to the U.S. dollar.

**Liquidity and Capital Resources**

We have incurred losses since our inception in October 1999, and, as of September 30, 2005, we had an accumulated deficit of \$82.6 million. We have funded our operations to date principally from proceeds from our initial public offering of common stock in December 2004 and private placements of equity securities and convertible promissory notes, raising aggregate net proceeds of \$162.7 million through September 30, 2005.

As of September 30, 2005, we did not have any outstanding or available debt financing arrangements, we had working capital of \$91.6 million and our primary source of liquidity was \$97.1 million in cash and cash equivalents. Pending their ultimate use, we currently invest our available funds in liquid money market accounts.

**Net Cash Used in Operating Activities**

Net cash used in operating activities was \$26.4 million during the nine months ended September 30, 2005. The net cash used during the nine months ended September 30, 2005 primarily reflected the net loss of \$38.1 million, partially reduced by stock-based compensation of \$9.1 million, increased accrued liabilities for legal expenses of \$1.8 million, increased inventories of \$1.4 million, net changes in other operating assets and liabilities of \$1.2 million, depreciation of \$0.7 million and increased clinical development liabilities of \$0.3 million.

Net cash used in operating activities was \$13.0 million during the nine months ended September 30, 2004. The net cash used during the nine months ended September 30, 2004 primarily reflected the net loss of \$15.8 million, partially reduced by stock-based compensation of \$2.8 million, depreciation of \$0.2 million and net changes in operating assets and liabilities of \$0.2 million.

**Net Cash Used in Investing Activities**

Net cash used in investing activities increased to \$3.1 million for the nine months ended September 30, 2005, from \$1.1 million for the nine months ended September 30, 2004, primarily as a result of increased purchases of property and equipment.

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities for the nine months ended September 30, 2005 was \$9.0 million, primarily due to the net proceeds we received from the sale and issuance of shares of our common stock upon the exercise of the over-allotment option by the underwriters of our initial public offering in January 2005. Net cash provided by financing activities for the nine months ended September 30, 2004 was \$39.2 million, primarily due to the net proceeds we received from the sale and issuance of our Series E convertible preferred stock.

Table of Contents***Operating Capital and Capital Expenditure Requirements***

As of September 30, 2005, we had not recognized a significant amount of revenue from commercial product sales and we had not achieved profitability. We anticipate that we will continue to incur net losses for the next several years as we develop new products, expand our clinical development team and corporate infrastructure and prepare for the potential broader commercialization of our CoStar stent. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues or raise additional capital to achieve profitability.

We do not expect to generate significant product sales until we successfully obtain marketing approval for and begin selling our CoStar stent in the European Community. We believe that our cash and cash equivalent balances as well as the interest we earn on these balances and revenues from future product sales will be sufficient to meet our anticipated cash requirements through at least the first half of 2007. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to liquidate some or all of our assets or reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

We anticipate spending at least \$16.0 million over the next two years for clinical trials to obtain regulatory approvals of our CoStar stent. We estimate that the development of any new product candidates will cost between \$15.0 million and \$25.0 million per product candidate and will take up to four years to complete. We expect to fund the development of potential product candidates with our existing cash and cash equivalent balances or with cash received from sales of our securities.

Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under "Risk Factors" below. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of drug eluting stents, such as our CoStar stent, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the costs of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the costs of building commercial scale manufacturing capabilities;
- the costs and timing of regulatory approvals;
- the costs and timing of establishing sales, marketing and distribution capabilities;
- licensing technologies for future development;

- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands seeking a declaration that our CoStar stent infringes Angiotech's patent rights. In the suit, Angiotech and Boston Scientific are also seeking orders, among other things, preventing us from commercializing our CoStar stent in many European countries and requiring us to pay damages. Also, on November 8, 2005, Boston Scientific and Boston Scientific Scimed, Inc. (Scimed) initiated legal proceedings against us in the District Court for the District of Delaware seeking a judgment that our CoStar stent infringes U.S. Patent No. 5,922,021, one of the Jang patents assigned to Boston Scientific. In the suit, Boston Scientific and Scimed are also seeking orders, among other things, preventing us from commercializing our CoStar stent in the United States and requiring us to pay damages. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, we believe that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of our CoStar stent. A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market, such as Johnson & Johnson, Boston Scientific and Guidant Corporation. Several of these third-party patents have been or are being asserted in litigation against purported infringers, including against us, demonstrating a willingness by the patent owners to litigate their claims. Any lawsuit could seek to enjoin, or prevent, us from commercializing our CoStar stent and may seek damages from us, and would likely be expensive for us to defend. We have also received letters from third parties, some of whom have been actively involved in coronary stent litigation, asserting that they may have rights to patents that are relevant to our operations or our stent platform and requesting the initiation of discussions. A court may determine that these patents are valid and infringed by us. A finding that we infringe any valid claim in a patent held by a third party would have a material adverse effect on our results of operations, financial condition and liquidity, and we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our CoStar stent, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

An award of damages against us would adversely affect our results of operations and liquidity, and any delays or restrictions with respect to our commercialization plans resulting from such litigation would adversely affect our ability to generate revenues. In addition, our competitors have significant resources to devote to litigation against us, and we may need to expend significant resources to defend such litigation. We could require significant additional funds to bear the costs of this litigation, regardless of whether we prevail. Our ability to continue to operate under our current operating plan could be impaired if such funds are not available. Since our costs in connection with any such litigation will vary greatly depending on the nature and timing of the litigation, it is not possible to estimate the effect of any such costs on our financial condition and results of operations. Amounts ultimately payable, if any, resulting from an adverse outcome of any of these matters cannot be reasonably estimated at this time.

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**Contractual Obligations**

The following table summarizes our outstanding contractual obligations as of September 30, 2005 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments due by period			
	Total	Less than 1 Year	1-3 Years	More than 3-5 Years 5 Years
Operating Leases	\$5,303	\$1,120	\$ 1,952	\$ 663 \$ 1,568

The table above reflects only payment obligations that are fixed and determinable. Our commitments for operating leases relate to the lease for our headquarters in Menlo Park, California and for our facility in Athlone, Ireland.

In February 2005, we entered into a ten-year operating lease, which has an option for an additional ten years, for manufacturing facilities in Athlone, Ireland. Total future minimum lease payments are \$3.3 million. The lease payments for our facilities in Ireland are denominated in euros and have been converted into U.S. dollars using the exchange rate in effect as of September 30, 2005.

In March 2005, we entered into an amendment of the lease agreement for our current headquarters in Menlo Park, California. The amendment provides for an additional 26,000 square feet of space in a building adjacent to our current headquarters and extends the term of our lease for an additional year to August 2008. Total future minimum lease payments are \$2.0 million.

**Recent Accounting Pronouncements**

In December 2004, the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123R") which is a revision of SFAS No. 123, and supersedes APB Opinion 25. SFAS No. 123R requires all share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values, beginning with the first annual period after June 15, 2005, with early adoption encouraged. On April 14, 2005, the SEC adopted a new rule that amended the compliance dates for SFAS No. 123R such that we are now allowed to adopt the new standard effective January 1, 2006. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. As permitted by SFAS No. 123, we currently account for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, recognize no compensation cost for employee stock options.

Under SFAS No. 123R, we must determine the appropriate fair value model and related assumptions to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are currently evaluating the requirements of SFAS No. 123R as well as option valuation methodologies related to its employee and director stock options and employee stock purchase plan. Although we have not yet determined the method of adoption or the effect of adopting SFAS No. 123R, it is expected that the adoption of SFAS No. 123R will have a material impact on our consolidated results of operations. The impact of adoption of SFAS No. 123R cannot be predicted at this time because it will



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depend on, among other things, the levels of share-based payments granted in the future, the method of adoption and the option valuation method used. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation costs to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* ("SFAS No. 154"), a replacement of APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS No. 154 changes the requirements related to accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and changes required by a new accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. Under SFAS No. 154, we must record the impact of a change in accounting principle retrospectively to financial statements of prior periods. Previously, the guidance allowed the recording of the impact of an accounting change in the current period's net income as a cumulative effect adjustment. SFAS No. 154 is effective for us beginning January 1, 2006. The adoption of SFAS No. 154 is not expected to have a material impact on our consolidated earnings, financial position or cash flows.

**Risk Factors**

*We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.*

**Risks Related to Our Intellectual Property**

Intellectual property rights, including in particular patent rights, play a critical role in the drug eluting stent sector of the medical device industry, and therefore in our business. We face significant risks relating to patents, both as to our own patent position as well as to patents held by third parties. These risks are summarized below. We have described in greater detail our patent position, and patents held by third parties that could impact our business, under "Item 1. Business—Patents and Proprietary Rights" in our Annual Report on Form 10-K for the year ended December 31, 2004, filed with the SEC on March 31, 2005. You should consider carefully the matters discussed under that caption and in the risk factors below in considering an investment in our common stock.

***If any patent infringement or other intellectual property claims asserted against us are successful, we could be enjoined, or prevented, from commercializing our CoStar stent or other product candidates.***

There are numerous U.S. and foreign issued patents and pending patent applications owned by third parties with patent claims in areas that are the focus of our product development efforts. We are aware of patents owned by third parties, to which we do not have licenses that relate to, among other things:

- use of paclitaxel (in general or on a stent) to treat restenosis;
- stent structure;
- catheters used to deliver stents;
- composition of materials used on or with stents; and
- stent manufacturing processes.

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A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market, such as Boston Scientific Corporation, Johnson & Johnson and Guidant Corporation. Several of these third-party patents have been or are being asserted in litigation against purported infringers, including against us, demonstrating a willingness by the patent owners to litigate their claims. On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands seeking a declaration that our CoStar stent infringes European Patent No. 0 706 376 B1, one of the Hunter patents owned by Angiotech and licensed to Boston Scientific. In the suit, Angiotech and Boston Scientific are also seeking orders, among other things, preventing us from commercializing our CoStar stent in many European countries and requiring us to pay damages. Also, on November 8, 2005, Boston Scientific and Boston Scientific Scimed, Inc. (Scimed) initiated legal proceedings against us in the District Court for the District of Delaware seeking a judgment that our CoStar stent infringes U.S. Patent No. 5,922,021, one of the Jang patents assigned to Boston Scientific. In the suit, Boston Scientific and Scimed are also seeking orders, among other things, preventing us from commercializing our CoStar stent in the United States and requiring us to pay damages. We are unable to predict the outcome of these legal proceedings. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to other large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, we believe that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of our CoStar stent based on one or more of these or other patents. We have also received letters from third parties who have intellectual property rights in, or who have been actively involved in litigation or oppositions relating to, coronary stents, asserting that they may have rights to patents that are relevant to our operations or our stent platform and requesting the initiation of discussions. Any lawsuit could seek to enjoin, or prevent, us from commercializing our CoStar stent and may seek damages from us, and would likely be expensive for us to defend. A court may determine that these patents are valid and infringed by us. For a description of patents that we consider to pose a material litigation risk to us, see the discussion under the caption "Business—Patents and Proprietary Rights—Third-Party Patent Rights" in our Annual Report on Form 10-K for the year ended December 31, 2004, filed with the SEC on March 31, 2005. There may be patents in addition to those described under that caption that relate to aspects of our technology and that may materially and adversely affect our business. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that pose a material risk to us.

The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. Some of the companies in these markets, such as Boston Scientific, Johnson & Johnson and Guidant, have been able to capture significant market share by introducing new technologies. These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and potential new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific, Johnson & Johnson, Guidant and Medtronic Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. Ongoing patent litigation includes litigation between Boston Scientific and Johnson & Johnson relating to Boston Scientific's drug eluting stent and Johnson & Johnson's drug eluting stent. Each company is claiming that the other company infringes its intellectual property. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies, especially Boston Scientific and others against which we would compete directly, have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our CoStar stent and as indicated above, Angiotech and Boston Scientific have initiated legal proceedings in the Netherlands against us seeking to prevent us from commercializing our CoStar stent in certain European countries, and Boston Scientific and Boston Scientific Scimed have initiated legal proceedings in Delaware against us seeking to prevent us from commercializing our CoStar stent in the United States. Boston Scientific also owns a series of patents, known as the "Kunz" patents, which cover the use of paclitaxel to treat restenosis generally and also to treat restenosis via a stent. It is possible that Boston Scientific could assert a patent infringement claim against us based on these patents.

Angiotech is the owner of a number of patents, sometimes referred to as the "Hunter" patents, and has licensed from the U.S. government a number of other patents, sometimes referred to as the "Kinsella" patents, that also claim the use of paclitaxel coated stents to treat angiogenesis and restenosis. Angiotech granted an exclusive license to Boston Scientific under these patents in the coronary vascular field of use. The legal proceedings initiated by Angiotech and Boston Scientific against us in the Netherlands allege that the CoStar stent infringes one of the Hunter patents.

Boston Scientific owns other patents that may have a material adverse affect on us. These include the "Jang" stent structure patents, including patents with claims covering a stent with a plurality of cavities which are micro-holes or micro-slits which act as reservoirs for a substance and claims covering an expandable stent having expansion columns and connecting strut columns. The legal proceedings initiated by Boston Scientific and Boston Scientific Scimed against us in Delaware allege that our CoStar stent infringes one of the Jang patents.

In addition, Guidant owns a number of patents that could have a material adverse effect on us. These include the "Yock" family of patents that are directed to rapid exchange catheters, the "Lau" family of patents which claim rapid exchange catheters for stent delivery, another "Lau" family of patents directed to stent structures and the "Castro" patents, which are directed to a manufacturing process involving the application of a material to a stent.

While our products are in clinical trials, and prior to commercialization, we believe that our activities in the United States related to the submission of data to the FDA fall within the scope of the exemptions that cover activities related to developing information for submission to the FDA and fall under general investigational use or similar laws in other countries. However, the U.S. exemptions may not cover our stent manufacturing or other activities in the United States if those activities are not also reasonably related to developing information for submission to the FDA.

Whether we would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets the patent claim in the context of litigation. If an infringement allegation is made against us, we may seek to invalidate the asserted patent claim and/or to allege non-infringement of the asserted patent claim. In Europe, individual country laws control the standard for patent invalidation, and the burden of proof to invalidate a particular claim can vary among countries. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to issued patents in the United States with clear and convincing evidence of invalidity, which is a high burden of proof. In February 2005, we initiated legal proceedings in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376 B1, which is one of the Hunter patents owned by Angiotech and licensed to Boston Scientific that is the subject of the legal proceedings asserted against us in the Netherlands. The trial began on October 4, 2005, and the High Court of Justice is expected to hear the parties' closing arguments in mid December 2005. We anticipate that the High Court of Justice will deliver its decision in early 2006. We are unable to predict the outcome of these proceedings.

In the event that we are found to infringe any valid claim in a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our CoStar stent, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.